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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,289	10/15/2003	Ivan Osorio	011738.00141	8969

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EXAMINER

ALTER, ALYSSA M

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,289

Applicant(s)

OSORIO ET AL.

Examiner

Alyssa M Alter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/15/03.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/10/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 1-12 and 13-37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The examiner recommends changing "implanted" in claims 1 and 13 to "implantable".

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-14, 23-31 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulman et al. (US 6,208,894). Schulman et al. discloses a system in Figure 1 and 2 that incorporates several implantable devices, one being a system control unit (SCU) 302, an external clinician's programmer 172 and an external patient control unit 174.

As to claims 1, 4, 11 and 28, since the SCU is implanted in the patient's body, it is considered the implanted component. The SCU communicates with other implanted devices 100, such as stimulators 100a and 100b, a sensor 100c and a transponder 100d. "Each said implanted device is configured to be monitored and/or controlled by

the SCU via a wireless communication channel”(col. 1, lines 37-39). Communication that results in monitoring and/or controlling is considered by the examiner to be a feature.

The features of the system are displayed in figure 2. The first feature is the communication between transmitter 304 and the implanted devices 100. The second feature is the communication between the transceiver 314 and both the clinician's programmer 172 and the patient control unit 174. The third feature is the communication between the implanted devices 100 and the receiver 306. The fourth feature is the clinician's programmer 172 and the body, more specifically the transponders 100d implanted within the body. The fifth feature is the communication between the clinician's programmer 172 and the patient control unit 174.

As to claims 2, 3 and 23, programming of the SCU is the second feature. Indirect programming can be accomplished by using the translation table 340. “The use of the translation table 340 is optional since the intermediary addresses can, instead, be programmed directly into a control program contained in the program storage 310”(col. 10, lines 29-32). The programming of the SCU, either indirect or directly affects how the third feature, communication between the implanted devices 100 and the receiver 306, is utilized. For example in closed loop mode, the information received by the third feature regulates the SCU commands that it issues to other implanted devices.

As to claim 5, the “external devices can communicate with the SCU 302 via a transceiver 314 coupled to the programmable controller 308” (col. 5, lines 36-38). The

transceiver 314 acts as the "relaying module" when interacting with one or both of the external components 172 and/or 174.

As to claim 6, "In accordance with a significant feature of the preferred embodiment, the SCU and/or each implantable device includes a programmable memory for storing a set of default parameters"(col. 2, lines 30-33).

As to claims 7 and 8, "Transponders, e.g., 100d, are devices which can be used to extend the interbody communication range between stimulators and sensors and other devices, e.g., a clinician's programmer 172 and the patient control unit 174" (col. 4, lines 17-21). Therefore the transponders are the forth feature, which the examiner considers to also be a triggering device since it affects the other features. A second channel of communication is established from the clinician's programmer 172 to the transponders 100d.

As to claims 9-10 and 12, figure 2 shows the clinician's programmer 172 supporting the patient control unit 174. The communication between these to external devices is the fifth feature of the system. "The patient control unit 174 typically communicates with the implanted devices 100, e.g., microsensors 100c, to monitor biological parameters"(col. 4, lines 38-40).

As to claim 13, 26 and 29, "each device can be separately configured, controlled and/or sensed as part of a system for controlling one or more neural pathways within a patient's body"(col. 8, lines 27-29). Since the device is capable of treating "neural pathways" it can inherently be used to treat the peripheral nerve and the peripheral nervous system.

As to claim 14, "While the translation table 340 can be remotely programmed, e.g., via a modulated signal from the clinician's programmer 172, it is also envisioned that the SCU 302 can reprogram the translation table 340 if the communications degrade"(col. 10, lines 39-43). Therefore, the system has capabilities of detecting if the communication between the clinician's programmer 172 and the SCU 302 is defective.

As to claims 24 and 25, Schulman et al. utilizes both hybrid and external systems. According to figure 2 the external system is with the clinician's programmer 172 and/or the patient control unit 174. Since the external system(s) can be used in conjunction with the SCU, that creates a hybrid system.

As to claim 27, since the implanted devices 100 can be implanted anywhere within the body to assist with "controlling one or more neural pathways" (col. 8, lines 28-29), it could inherently be used to treat a nervous system disorder, such as Parkinson's disease.

As to claims 30-31 and 35, the first feature, communication with the implanted devices 100, can operate in open loop mode where the SCU 302 is programmed by the clinician's programmer 172, the second feature, "to periodically initiate tasks, e.g., perform real time tasking, such as transmitting commands to microstimulators according to a prescribed treatment regimen or periodically monitor biological parameters to determine a patient's status or the effectiveness of a treatment regimen" (col. 4, lines 50-54).

As to claim 36, the second feature where the clinician's programmer 172 communicates with the transceiver 314 can receive programming tasks and transfer

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information from the clinician's programmer 172. Figure 2, shows that the first feature is only a one way communication with the SCU 302 to the implanted devices 100, while the second feature is a two way communication. Therefore, the second feature has another functionality besides assisting in the programming and functioning of the implanted devices 100.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 15 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (US 6,208,894). Schulman et al. teaches the device substantially as claimed, but fails to teach the first feature corresponds to an open-loop treatment therapy and the second feature corresponds to a closed-loop treatment therapy. However, Schulman et al. does disclose that the clinician's programmer 172, through the second feature, is capable of programming the SCU 302 operation. This includes programming the SCU 302 to operate in either an open or closed loop capacity. As long as it was initially programmed to operate in this capacity, then it will continue even if the connection degrades.

2. Claims 16-19 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (US 6,208,894) in view of Fabian et al. (US

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6,735,479). Schulman et al. teaches the device substantially as claimed by fails to teach a loop recorder. Fabian et al. discloses the incorporation of a loop recorder with a lifestyle management system that can be added to an "implantable medical devices (IMDs, i.e., PCD, pacemaker, neurostimulator, drug pump, ILR, Chronicle monitor, etc.)" (col. 1, lines 49-51). Using a loop recorder would facilitate a recording of significant neurological data and other biological data for storage and/or transfer to an external monitor. Since the system with a loop recorder is used in combination with an implantable device, it would have been obvious at the time of invention to incorporate a loop recorder with the implanted SCU device system.

As to claim 32 and 33, since the lifestyle management system can be coupled with a drug pump, the modified Schulman et al. device would consequently be capable of distributing a pharmaceutical agent for treatment in addition to treating the patient with electrical stimulation.

3. Claims 20 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (US 6,208,894) in view of Massicotte et al. (US Patent Publication 20040068195). Schulman et al. teaches the device substantially as claimed by fails to teach an alarm or location system. Massicotte et al. discloses a locating module 112 and an emergency alarm transmitter 111 as see in figure 1 that "at any point, the stored data can be sent to a central monitoring station for review using the emergency alarm transmitter 111. The locating module 112, which automatically takes the GPS positioning 221 of the patient every minute, tries to obtain the position again. If the last position is accurate, the system uses that location" (page 4, paragraph 52). Since the

SCU device monitors biological data signals, it would be obvious to have a form of notification if there was an event that would require medical attention. Therefore it would have been obvious at the time of invention to incorporate an alarm system to notify the patient or medical help if an event was occurring and to have a location system to help the medical help locate the patient.

3. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (US 6,208,894) in view of Kaib (US 6,169,387). Schulman et al. teaches the device substantially as claimed by fails to teach a method of monitoring the connection between the implanted component and the external component to determine if they have become uncoupled. Kaib, in column 5 lines 29-31, discloses an alarm system to alert the patient if one of the sensing electrodes has become disconnected. Since an insufficient connection between the implanted device and the external device would interfere with the programming of the implanted device, a warning system to inform the programmer of this inadequacy would be advantageous. Therefore, it would have been obvious at the time of invention to incorporate a warning system into the Schulman et al. device in order to inform the programmer of the insufficient connect between the implanted and external devices.

Claim Objections

1. Claim 31 is objected to because of the following informalities: The examiner recommends changing the second "(e)" to "(f)". Appropriate correction is required.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M Alter whose telephone number is (703) 605-1156. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M. Alter
Alyssa M Alter
Examiner
Art Unit 3762


JEFFREY R. JASTRZAB
PRIMARY EXAMINER

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11/1/07